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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/978,217	11/25/1997	CHRISTOPHER C. BENZ	02307E-07111	4060

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EXAMINER

HOLLERAN, ANNE L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/978,217

Applicant(s)

BENZ ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-13, 16-18, 21-26, 71, 79 and 82-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 88 and 89 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-13, 16-18, 21-26, 71, 79 and 82-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 09/16/2004 is acknowledged. Claims 1 and 16 were amended.
2. Claims 1-4, 6-13, 16-18, 21-26, 71, 79, and 82-89 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn:

4. The rejection of claims 1-4, 6-9, 16-19 and 21-26 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claims.
5. The rejection of claims 1 and 16 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for introduction of new matter into the specification, is withdrawn in view of the amendment to the claims.

Claim Rejections Maintained:

6. The rejection of claims 1, 4, 6-13, 16, 21-26, 71, 79, and 82-85 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained, because it is not clear if the functional language “encodes a transcription factor a transcription factor that binds to and transactivates the Her-2/neu Ets response element” is descriptive of SEQ ID NO: 1 or descriptive of the claimed nucleic acid. See New Grounds of Rejection, under 112, second paragraph.

7. The rejection of claims 1, 2, 6-13, 21-26, 79, and 82-87 under 35 U.S.C. 102(e) as being anticipated by Kola et al, (U.S. Patent 5,789,200; issue Aug. 4, 1998; effective filing date Oct. 31, 1996) is maintained for the reasons of record, and applied to claim 16.

Claim 16 is rejected (as were previously rejected claims 21-26, which depend from claim 16) because it is broadly interpreted to read on nucleic acids that comprise nucleic acid molecules that encode fragments of a transcription factor having the amino acid sequence consisting of the amino acid sequence of SEQ ID NO: 2, which is the same sequence as the polypeptide of Kola.

Applicant presents no specific arguments why this rejection should be withdrawn. Applicant's comments with regard to providing a declaration under 37 C.F.R. 1.131 are noted. However, applicant's attention is drawn to MPEP 2308.01 that instructs applicant to file a statement under 37 C.F.R. 1.608(a) or 37 C.F.R. 1.608(b) when a patent claims the same

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invention as what is claimed in an application to another. See also MPEP 2138.03: Interference practice operates to the exclusion of ex parte practice under 37 CFR 1.131 which permits an applicant to show an actual date of invention prior to the effective date of a patent or literature reference applied under 35 U.S.C. 102(a) or (e), as long as the patent is not a domestic patent claiming the same patentable invention. Ex parte Standish, 10 USPQ2d 1454, 1457 (Bd. Pat. App. & Inter. 1988) (An application claim to the “same patentable invention” claimed in a domestic patent requires interference rather than an affidavit under 37 CFR 1.131 to antedate the patent. The term “same patentable invention” encompasses a claim that is either anticipated by or obvious in view of the subject matter recited in the patent claim.). Subject matter which is available as prior art only under 35 U.S.C. 102(g) is by definition made before the applicant made his invention and is therefore not open to further inquiry under 37 CFR 1.131.

New Rejections/Objections:

8. Claims 1-4, 6-13, 16-18, 21-26, 71, 79, and 82-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 16 are further indefinite because the it is not clear that the functional limitation, “encodes a transcription factor that binds to and transactivates the Her-2/neu Ets response element” is a description of SEQ ID NO: 1 or a description of the claimed nucleic acid. This rejection would be obviated if the claims were amended to recite “, and wherein the nucleic acid encodes a transcription factor that binds to and transactivates the Her-2/neu Ets response element.”

Claims 1 and 16 are indefinite because they are drawn to nucleic acids that hybridize to a sequence that the specification teaches is a coding sequence (for claim 1, SEQ ID NO: 1 and claim 16, SEQ ID NO: 15), wherein the same nucleic acid that hybridizes to the coding sequence, and is therefore, a non-coding sequence, “encodes a transcription factor”. This appears to be a contradiction. This rejection would be obviated if claims 1 and 16 were amended to recite that the claimed nucleic acid “specifically hybridizes under stringent conditions comprising washes at 65°C in 0.1x SSC to the *complete complement* of a *polynucleotide* consisting of the sequence of SEQ ID NO: 1, and that...”

Claims 1 and 16 are indefinite because the claims use the term “nucleic acid” in reference to at least two different nucleic acids. Therefore, it is unclear which nucleic acid is claimed in dependent claims that recite “the nucleic acid of claim 1”, or “the nucleic acid of claim 16”. This rejection may be obviated by amending claim 1 and claim 16 to recite “An isolated nucleic acid comprising a nucleic acid that specifically hybridizes under stringent conditions comprising washes at 65°C in 0.2 x SSC to a *polynucleotide* consisting of the sequence...”

Claim 79 is indefinite because it is drawn to a kit for detection of an ESX gene or polypeptide, where the kit comprises nucleic acids. The specification fails to teach how nucleic acids may be used in a kit having the purpose of detecting a polypeptide.

Furthermore, claim 79 is indefinite because of the phrase “hybridizes under stringent conditions”. The specification fails to define the limits of “stringent conditions”. While the specification contains examples of what is considered stringent conditions, a teaching of an example is not adequate to define the metes and bounds of the polynucleotides encompassed by

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claims because the specification fails to teach what falls within “stringent conditions” and what does not.

9. Claim 79 is rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim Biochemicals (1994 Catalog).

Claim 79 is drawn to a kit comprising a container containing a nucleic acid that specifically hybridizes under stringent conditions to a nucleic acid of claim 1. Stringent conditions are not defined in either the claims or the specification.

Boehringer Mannheim Biochemicals teaches a kit comprising a container of all possible hexanucleotides, which would contain nucleic acids that would hybridize to a nucleic acid of claim 1 (see page 91, Catalog no. 1277 081). Therefore, Boehringer Mannheim Biochemicals teaches a kit that is the same as that claimed.

10. Claims 79, and 83-85 are rejected under 35 U.S.C. 102(b) as being anticipated by ICN Biomedicals, Inc. (1990-'91 Catalog).

Claims 79 and 83-85 encompass kits comprising labeled nucleic acids.

ICN Biomedicals kits comprising containers of ³²P labeled deoxyribonucleotide triphosphate mixtures (page RC-96, #33030H) or containing ³²P labeled ribonucleotide triphosphate mixtures (page RC-99, #32040H). Deoxyribonucleotides or ribonucleotides would hybridize to a nucleic acid of claim 1. Therefore, ICN Biomedicals teaches kits that are the same as that claimed.

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Conclusion

Claims 88 and 89 are allowable. Claims 1-4, 6-13, 16-18, 21-26, 71, 79, and 82-87 are rejected.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
December 28, 2004

Alana M. Harris
ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER
01/03/2004